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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/398,405	09/16/99	SALERNO J	JCS96-01Z

HM22/1219

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1642	6

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/398,405	Salerno
Examiner	**Group Art Unit**
Ungar	1642

☒ Responsive to communication(s) filed on *Sep 16, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-59* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-59* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-59 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4315. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1, 2, 3, 6, 7-11 are drawn to an agent that specifically inhibits a constitutive endothelial nitric oxide synthase classified in Class 530, subclass 300+. .

Group 2. Claims 1, 2, 4 and 12-15 are drawn to an agent that specifically inhibits constitutive neuronal nitric oxide synthase classified in Class 530, subclass 300+. Claims 12-15 will be examined as they are drawn to the invention of Group II.

Group 3. Claims 1 and 5 are drawn to an agent that specifically inhibits inducible nitric oxide synthase, classified in Class 530, subclass 300+.

Group 4. Claims 16-18 are drawn to an activator of endothelial nitric oxide synthase which antagonizes autoinhibition, classified in Class 530, subclass 387.1.

Groups 5-10. Claims 16 and 19 are drawn to an activator of endothelial nitric oxide synthase wherein the activator is SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, respectively. Each invention is also drawn to activating fragments and derivatives of the claimed sequence , classified in Class 530, subclass 300. The elected invention will be examined as it is drawn to activation of endothelial nitric oxide synthase. If these inventions are not drawn to the activation of endothelial nitric oxide synthase, Applicant is required to identify which synthase they are drawn to so that the inventions can be properly restricted.

Group 11. Claims 20-22 are drawn to an activator of neuronal nitric oxide synthase which antagonizes autoinhibition classified in Class 530, subclass 387.1

Group 12-20. Claims 23 and 24 are drawn to an antibody which binds to an amino acid sequence wherein the amino acid sequence is SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8 and SEQ ID NO:9, respectively. Classified in Class 530, subclass 387.1

Group 21-29. Claim 25 is drawn to an isolated nucleic acid encoding an antibody which binds to an amino acid sequence wherein the amino acid sequence is SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4,

SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8 and SEQ ID NO:9, respectively. Classified in Class 530, subclass 387.1

Group 30. Claims 26, 27, 29 and 30 are drawn to a method of inhibiting endothelial nitric oxide synthase classified in Class 514, subclass 2.

Group 31. Claims 26 and 28 are drawn to a method of inhibiting neuronal nitric oxide synthase classified in Class 514, subclass 2.

Group 32-38. Claim 31 is drawn to a method of activating endothelial nitric oxide synthase wherein the activator is an antibody or peptide of SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID:9, respectively classified in Class 424, 130.1 and Class 514, subclass 2. Each invention is also drawn to activating fragments and derivatives of the claimed sequence , classified in Class 530, subclass 300. The elected inventions will be examined as it is drawn to activation of endothelial nitric oxide synthase. If these inventions are not drawn to the activation of endothelial nitric oxide synthase, Applicant is required to identify which synthase they are drawn to so that the inventions can be properly restricted.

Groups 39-44. Claim 32 is drawn to a method of activating endothelial nitric oxide synthase wherein the activator is a peptide comprising, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID:9, respectively classified in Class 514, 2. Each invention is also drawn to activating fragments and derivatives of the claimed sequence , classified in Class 530, subclass 300. The elected inventions will be examined as they drawn to activation of endothelial nitric oxide synthase. If these inventions

are not drawn to the activation of endothelial nitric oxide synthase, Applicant is required to identify which synthase they are drawn to so that the inventions can be properly restricted.

Group 45. Claim 33 is drawn to a method of activating endothelial nitric oxide by antagonizing autoinhibition by binding between amino acids 820 and 880, classified in Class 514, subclass 4.

Group 46. Claims 34-37 are drawn to an agent that inhibits inducible nitric oxide synthase by blocking electron transfer from NADPH to an active site, classified in Class 514, subclass2.

Groups 47-48. Claim 38 is drawn to an activator of endothelial nitric oxide synthase which binds to one or more amino acids in sequence of SEQ ID NO:21, SEQ ID NO:24, respectively, classified in Class 514, subclass 2. Each invention will be examined as it is drawn to the respective elected Group.

Groups 49-51. Claim 39 is drawn to an activator of inducible nitric oxide synthase which binds to one or more amino acids in sequence of SEQ ID NO:2, SEQ ID NO:22, SEQ ID NO:25, respectively, classified in Class 514, subclass2.. Each invention will be examined as it is drawn to the respective elected Group.

Group 52. Claim 40-41 is drawn to antibody that inhibits inducible nitric oxide synthase classified in Class 424, subclass 130.1

Group 53. Claim 40-42 is drawn to antibody that activates inducible nitric oxide synthase classified in Class 424, subclass 130.1

Group 54. Claims 44-45 are drawn to method of treating a disease comprising administering an inhibitor of neuronal oxide synthase, classified in Class 514, subclass 2.

Group 55. Claims 43, 45-47 are drawn to method of treating a disease comprising administering an inhibitor of endothelial nitric oxide synthase, classified in Class 514, subclass 2.

Group 56-61 Claim 48 is drawn to a method of treating a disease with an antibody against, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID:9, respectively classified in Class 424, 130.1 and Class 514, subclass 2. Each invention is also drawn to activating fragments and derivatives of the claimed sequence , classified in Class 530, subclass 300. The elected inventions will be examined as they are drawn to treatment by activation of endothelial nitric oxide synthase. If these inventions are not drawn to treatment by the activation of endothelial nitric oxide synthase, Applicant is required to identify which synthase they are drawn to so that the inventions can be properly restricted.

Groups 62-67. Claims 49-50 are drawn to a method of treating a disease with a peptide comprising, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID:9, respectively classified in Class 514, 2. Each invention is also drawn to activating fragments and derivatives of the claimed sequence , classified in Class 530, subclass 300. The elected inventions will be examined as they drawn to treatment by activation of endothelial nitric oxide synthase. If these inventions are not drawn to

treatment by activation of endothelial nitric oxide synthase, Applicant is required to identify which synthase they are drawn to so that the inventions can be properly restricted.

Group 68-70. Claims 51-56 are drawn to method of identifying an agent that inhibits activity of nitric oxide synthase wherein the synthases are endothelial nitric oxide synthase, neuronal nitric oxide synthase and inducible nitric oxide synthase respectively, classified in Class 435, subclass 4.

Group 71-73. Claims 54-55 are drawn to method of identifying an agent that activates activity of nitric oxide synthase wherein the synthases are endothelial nitric oxide synthase, neuronal nitric oxide synthase and inducible nitric oxide synthase respectively, classified in Class 435, subclass 4.

Group 74. Claim 56 is drawn to method of identifying an agent that inhibits activity of inducible nitric oxide synthase wherein the synthases are endothelial nitric oxide synthase, neuronal nitric oxide synthase and inducible nitric oxide synthase respectively, classified in Class 435, subclass 4.

Group 75. Claims 57 is drawn to nucleic acid sequence encoding the peptide of claim 6, classified in Class 536, subclass 23.1.

Group 76. Claims 58 is drawn to nucleic acid sequence encoding the peptide of claim 12, classified in Class 536, subclass 23.1.

Group 77-82. Claims 57 is drawn to nucleic acid sequence encoding the peptide of SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID:9, respectively classified in Class 536, subclass 23.1.

Group 83 Claims 26 is drawn to a method of inhibiting inducible nitric oxide synthase classified in Class 514, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-29, 46-53 and 75-82 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 30-45, 74-57 and 83 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-3/52/46 and 30-31/54-70/74 and 79 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody/peptide products as claimed can be used in a materially different product, that is affinity chromatography.

The inventions of Groups 4-11/47-48/53 and 32-45/56-61/71-73 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see

MPEP § **806.05(h)**]. In the instant case the antibody/peptide products as claimed can be used in a materially different product, that is affinity chromatography.

The inventions of Groups 3/52 and 46 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody/peptide products as claimed can be used in a materially different product, that is affinity chromatography.

The inventions of Groups 4-29, 47-51, 53 and 75-82 are not at all related to the inventions of Groups 30-31, 54-70, 74 and 79 because the products of Groups 4-29, 47-51, 53 and 75-82 are not at all used in the methods of Groups 30-31, 54-70, 74 and 79.

The inventions of Groups 1-3, 12-19, 46, 49-52 and 75-82 are not at all related to the inventions of Groups 32-45, 56-61 and 71-73 because the products of Groups 1-3, 12-19, 46, 49-52 and 75-82 are not at all used in the methods of Groups 32-45, 56-61 and 71-73.

The inventions of Groups 1, 2, 4-19, 46-51, 53 and 75-82 are not at all related to the inventions of Group 46 because the products of Groups 1, 2, 4-19, 46-51, 53 and 75-82 are not at all used in the methods of Group 46.

The inventions of Groups 12-29, 49-51 and 75-82 are not at all related to any of the method Groups recited because the products of Groups 12-29, 49-51 and 75-82 are not used in any of those methods.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claims 6 is generic to a plurality of disclosed patentably distinct species comprising peptides with different structures and therefore different functions wherein the peptides are (a) SEQ ID NO:8 (claim 7), (b) SEQ ID NO:1 (claim 8), © SEQ ID NO:12 (claim 11), (d) SEQ ID NO: 12 (claim 11), (e) SEQ ID NO:13, (claim 11), (f) SEQ ID NO:14 (claim 11), (g) SEQ ID NO:15 (claim 11).

6. Group II is further subject to election of a single disclosed species.

Claims 12 is generic to a plurality of disclosed patentably distinct species comprising peptides with different structures and therefore different functions wherein the peptides are (a) SEQ ID NO:2 (claims 12 and 15), (b) SEQ ID NO:16 (claim 14), © SEQ ID NO:17 (claim 14), (d) SEQ ID NO: 18 (claim 14), (e) SEQ ID NO:19, (claim 14).

7. Group XXX is further subject to election of a single disclosed species.

Claims 27 is generic to a plurality of disclosed patentably distinct species comprising peptides with different structures and therefore different functions ~~wherein the peptides comprise (a) SEQ ID NO:8 (claim 29), (b) SEQ ID NO:1~~ (claim 30). The claims will be examined as they are drawn to inhibiting endothelial nitric oxide synthase.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

~~If attempts to reach the examiner by telephone are unsuccessful, the~~ examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
December 18, 2000